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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,687	01/03/2001	Karla M. Robotti	10991975-1	2886

7590 05/19/2003

AGILENT TECHNOLOGIES
Legal Department, 51U-PD
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EXAMINER	
GORDON, BRIAN R	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,687	ROBOTTI ET AL.	
	Examin r	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Oath/Declaration

1. A new oath or declaration is required because the filing date and application number is missing, there is no signature for the second listed inventor, and the declaration has been amended. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. OK

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4-5, 9, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 4, 9, and 15 recite that the porosity of the microvalve is modulated. It is unclear how the porosity of the microvalve is modulated. The examiner thinks that applicant's intent is to recite that the porosity of the phase reversible material included in the microvalve is actually modulated. Ok

6. Claim 5 recites the limitation "said at least one analyte" in line1. There is insufficient antecedent basis for this limitation in the claim. Ok

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch et al. US 5,746,901.

Balch et al. disclose a hybrid slab-microchannel gel electrophoresis system and the advantages of using thinner gels.

The advantages of thinner gels in allowing high-speed separations of DNA from sequencing reactions has recently been demonstrated by several groups using gel-filled capillary electrophoresis. In gel capillary electrophoresis the separation is typically done in a 50-100 um internal diameter quartz capillary which has much improved thermal dissipation over thicker slab gels. For example, using a 50 um i.d. capillary **(flow path)** operated at an electric field of 200 V/cm, there has been demonstrated a ten-fold

reduction in separation time of a DNA sample compared to the separation time required for the same sample using the ABI 373 DNA sequencer operated with a 400 um thick slab gel and run with a 30-37.5 V/cm applied electric field. Efforts to develop high-speed, high throughput automated DNA sequencers by combining many small diameter quartz capillaries (e.g. 10-100) have experienced many mechanical and electrical problems concerned with: 1) filling multiple capillaries with equally high quality gel **(phase reversible material)**; 2) loading the DNA samples into separate capillaries; **(introducing multi-component sample into microfluidic device having a flow path)**and 3) devising a sensitive optical detection system to measure the output fluorescence signals from all the very small capillaries. Other major factors limiting resolution of DNA fragments by electrophoresis include sample quality, sample loading on to the gel, and diffusion (separation of multi-component sample) of DNA through the gel prior to the time of detection. Recent progress in using pumpable low viscosity **polymer** sieving media may greatly reduce the problems of filling multiple capillaries systems.

The invention utilizes an electrically insulated or high resistance, high thermal conductivity substrates to support and encompass microgels used for electrophoretic separations.

Electrophoresis systems are typically comprised of a sieving matrix (i.e., polyacrylamide gel) sandwiched between two plates of glass. An electric field is applied **(applying stimulus to chang temperatur)** across the device thus providing the force necessary to separate molecules based upon their mobility in the sieving medium.

These plates are usually used repeatedly with only the sieving matrix being replaced between runs. Thus, one of the two plates of glass of a typical electrophoresis system would be provided with microchannels formed therein, thereby increasing the number of lanes on a single substrate or plate.

Particulary, Balch teaches a hybrid gel electrophoresis device and involves the use of slab gel and microchannel gel. The device permits the fabrication of isolated microchannels for biomolecule separations without imposing the constraint of a totally sealed system. This device is reusable and ultimately much simpler and less costly to manufacture than a closed channel plate system. This device can be used for separation and detection of a large class of biomolecules such as DNA fragments, DNA sequencing ladders and proteins. The invention involves a cost effective method of fabricating multiple use microchannel gel electrophoresis plates. Gel electrophoresis of biomolecules and DNA fragments have commercial application in research, forensics, and clinical diagnostics.

The microchannels are filled with a thin electrophoresis gel. The top plate of the device is of an optical quality that will, for example, transmit the laser-induced fluorescence of the fluorochrome labeled DNA fragments onto a sensitive optical detector.

Biomolecules are loaded into the microchannels (e.g. 50-400 micrometer deep) and are separated as they migrate down the channel.

9. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. US 5,770,029.

Nelson et al. disclose integrated electrophoretic microdevices comprising at least an enrichment channel and a main electrophoretic flowpath that includes gel separation media.

Electrophoretic gel media may also be employed as enrichment means in the subject applications. Gel media providing for a diversity of different sieving capabilities are known. By varying the pore size of the media, employing two or more gel media of different porosity, and/or providing for a pore size gradient and selecting the appropriate relationship between the enrichment channel and the main electrophoretic flowpath, one can ensure that only the analyte comprising fraction of interest of the initial sample enters the main electrophoretic flowpath. For example, one could have a device comprising an enrichment channel that intersects the main electrophoretic channel, where the enrichment channel comprises, in the direction of sample flow, a stacking gel of large porosity and a second gel of fine porosity, where the boundary between the gels occurs in the intersection of the enrichment channel and the main electrophoretic flowpath. In this embodiment, after sample is introduced into the stacking gel and an electric field applied to the gels in the enrichment channel, the sample components move through the stacking gel and condense into a narrow band at the gel interface in the intersection of the enrichment channel and main electrophoretic flowpath. A second electric field can then be applied to the main electrophoretic flowpath so that the narrow band of the enriched sample fraction moves into and through the main electrophoretic flowpath. Alternatively, the enrichment channel could comprise a gel of gradient porosity. In this embodiment, when the band(s) of interest reaches the intersection of

the enrichment channel and electrophoretic flowpath, the band(s) of interest can then be moved into and along the main electrophoretic flowpath.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al or Nelson et al.

Although it is not specifically recited that instructions are provided on a substrate, it would have been obvious to one of ordinary skill in art at the time of the invention to provide instructions or operational manuals that would explain to one that may desire to use the device to perform experimental procedures. It is also commonly known that manuals may be provided in the form of paper or electronic floppies or compact disks.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Robotti et al. discloses a chemico-mechanical microvalve.
Kopf Sill et al., Handique et al., Wildling et al., Chen et al., and Grenner et al. disclose liquid transport systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
May 14, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700